

OCT 27 2003

K 022730  
10fz

**K022730 - Perfadex® Solution for Lung Perfusion**

**510 (k) Summary**

Date Prepared: October 23, 2003

1. Sponsor

B. Sponsor Name

Vitrolife AB  
(subsidiary of Xvivo Transplantation Systems AB)  
Molndalsvagen 30, SE-412 63, Gothenburg, Sweden  
Tel: 46 31 721 8060 Fax: 46 31 721 8099

Contact Name: Mr. Hans Lehmann  
Regulatory Manager

C. Submission Correspondent

Karl Posselt  
FDA Regulatory Services  
155 Cider Mill Road  
Ringoes, NJ 08551  
Tel: (908) 284-2246 Fax: (908) 284-2246  
E-mail: eamwellkarl@yahoo.com

2. System Identification

A. Proprietary Name

Perfadex® Solution for Lung Perfusion

B. Common or Usual Name

Solution for Organ Preservation

C. Product Classification

Class II Panel No. 78 MSB

3. Predicate Device

A. Name

Classification Name: System & Accessories, Isolated Heart Transport and Preservation  
Regulation Number: 876.5880  
510(k) No. K000881  
Perfadex® Solution for Lung Perfusion  
Vitrolife AB

4. Perfadex® Device Information

A. Indications for Use

Perfadex® Solution for Lung Perfusion is indicated for the flushing, storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient.

B. Device Description

Perfadex® is a clear, sterile, non-pyrogenic, extracellular type solution for hypothermic flushing and storage of isolated lungs. The solution is slightly acidic (pH5.5) to permit long shelf life and is adjusted shortly before use to pH 7.4. The solution is slightly hypertonic (osmolarity 295 mOsm/L) and has a low buffering capacity. The composition of Perfadex® is thus consistent with that of an extracellular solution.

Perfadex® is filled into 1 or 2.8 liter PVC (Viaflex) bags, each of which is sealed in an outer polypropylene bag.

Manufacturing, control and sterilization is performed at an FDA inspected plant owned and operated by Fresenius Kabi Norge AS in Halden, Norway. The product is stored at room temperature.

Perfadex® is supplied with pre-filled, sterile, non-pyrogenic, syringes of THAM (tromethamine USP) for pH adjustment of the solution prior to use.

The pre-filled syringes of THAM are manufactured, packaged, labeled and controlled by Vitrolife UK Ltd., Edinburg, UK.

5. Substantial Equivalence

Perfadex® supplied with pre-filled syringes of THAM (tromethamine USP) for pH adjustment is substantially equivalent to Perfadex® in a 1 or 2.8 L PVC (Viaflex) bag K000881.



OCT 27 2003

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Vitrolife AB  
c/o Mr. Karl A. Posselt  
Submission Correspondent  
FDA Regulatory Services  
155 Cider Mill Road  
RINGOES NJ 08551

Re: K022730  
Trade/Device Name: Perfadex<sup>®</sup> Solution for Lung Preservation  
Regulation Number: 21 CFR §876.5880  
Regulation Name: Isolated kidney perfusion and transport system and accessories  
Regulatory Class: II  
Product Code: 78 MSB  
Dated: July 25, 2003  
Received: July 29, 2003

Dear Mr. Posselt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

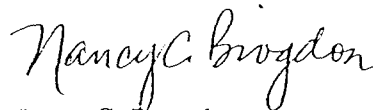
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>.

Sincerely yours,



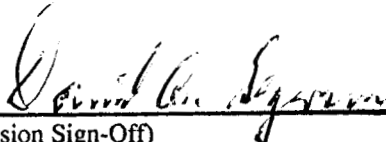
Nancy C. Brogdon  
Director, Division of Reproductive,  
Abdominal and Radiological Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

Statement of Indications For Use

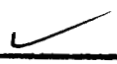
STATEMENT OF INDICATIONS FOR USE

Perfadex® Solution for Lung Perfusion is indicated for the flushing, storage and transportation of isolated lungs after removal from the donor in preparation for eventual transplantation into a recipient.



(Division Sign-Off)  
Division of Reproductive, Abdominal,  
and Radiological Devices

510(k) Number K022730

Prescription Use   
(Per 21 CFR 801.109)